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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/032,370 | 12/21/2001 | Jeffrey A. Trogolo | A-036 | 5277 |

7590 07/29/2005

AGION TECHNOLOGIES
60 Audubon Road
Wakefield, MA 01880

EXAMINER

EBRAHIM, NABILA G

ART UNIT PAPER NUMBER

1618

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/032,370 | TROGOLO ET AL. | |
| | Examiner | Art Unit | |
| | Nabila G. Ebrahim | 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/28/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-7, 10-22, 33, 34, 45 and 47-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-7, 10-22, 33, 34, 45 and 47-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged for IDS, request of RCE, and claim amendment all received on 1/28/2005

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10- 22, 33, 34, 45, 47-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al (US 6,436,422) "Trogolo" in view of Michael et al (US 6287285) "Michael" and Schink et al. (US patent application number 2001/0009831) "Schink"

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-7, 10, 22, 33, 34, 45, 47-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Trogolo" et al (US 6,436,422). Applicants claim a high aspect ratio microcapsule comprising an antimicrobial agent coated with a hydrophilic polymer, said microcapsule having an aspect ratio of greater than about 2. Applicants explain the aspect ratio as the ratio of the longest dimension of a three-dimensional particle to the shortest dimension. Generally, the high aspect ratio antimicrobial microcapsules include microcapsules that are in the shape of flakes or sheets as well as those that are in the shape of fibers or cylinders. Other shapes, such as football and other oblong shapes are suitable as well (instant specification page 5). Trogolo discloses an antibiotic coated substrate having an antibiotic coating composition coated thereon. The coating composition is formed of a hydrophilic polymer having antibiotic ceramic particles, preferably antibiotic zeolite dispersed therein (col. 2, lines 58-61) zeolite may further comprise a discoloration agent (abstract and col. 5, lines 22-26). Antibiotic ceramic particles include zeolites, hydroxyapatite, zirconium phosphates and other ion-exchange ceramics (col. 3, lines 21-24). Any suitable hydrophilic polymer may be employed, including hydrophilic polyurethane (col. 3 lines 35-42). In antibiotic zeolite particles used in the preferred embodiment, exchangeable ions present in zeolite, such as sodium ions, calcium ions, potassium ions and iron ions are partially replaced with ammonium and antibiotic metal ions. Such ions may co-exist in the antibiotic zeolite particle since they do not prevent the bactericidal effect (col. 3, lines 52-59). Examples of antibiotic metal ions include, ions of silver, copper, zinc, mercury tin, lead, bismuth,

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cadmium, chromium and thallium (col. 3, lines 59-63). Preferably, the antibiotic metal ions are silver, copper, or zinc ions, and most preferably silver is employed. These antibiotic metal ions may be incorporated into the zeolite by themselves or in a mixture (col. 3 lines 21-65). A discoloration agent may be added to the antibiotic hydrophilic polymer. The inorganic discoloration inhibitor is an ion-exchanged ammonium ion in the antibiotic zeolite. The substrate may be any substrate to which the hydrophilic polymer adheres, including glass, plastic, metal, and woven and non-woven fabrics. An article comprising a substrate on which is coated with the antibiotic hydrophilic coating may also be used. The article may be a medical article, such as a catheter, stent, heart valve, or paper (col. 5, lines 22-55).

The solids in the coating solution preferably contain from about 0.01 to about 90% by weight of antibiotic zeolite and from about 10% to about 99.99% by weight of hydrophilic polymer (col. 6, lines 13-23). Trogo is being deficient in reciting a microcapsule in his claims.

"Schink" disclosed an antimicrobial wound covering comprising a synthetic polymer material containing zeolites and metal ions (abstract). The coverings may be used to treat infected wounds or for preventive protection against wound infections. "Schink" disclosed in his application that, It has been disclosed in the "Schnik" that the zeolites may be incorporated into polyurethanes by admixing the zeolite to the polyurethane base materials, without disrupting the reaction, and that they are able to develop their antimicrobial action [0051]. The Schink

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application has disclosed also that their invention is made of particles [0066, 0067].

Trogolo is also silent with regards to the aspect ratio, specifically an aspect ratio greater than about 2. While the reference is silent regarding the aspect ratio, difference in the aspect ratio will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such an aspect ratio is critical. Where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Trogolo discloses the similar coated particles as desired by Applicants. Trogolo discloses sheets, fibers and cylinders (Figure 1 and col.5). Therefore, absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the shapes invented by Trogolo and apply it inside a particle motivated by the teaching of Schink to determine a suitable aspect ratio to achieve the desired results.

Claims 1-22, 33-34, 45-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. (US 6, 436, 422) in view of Michal et al. (US 6,287,285). Applicants claim a high aspect ratio microcapsule comprising an antimicrobial agent coated with a hydrophilic polymer, said microcapsule having an aspect ratio of greater than about 2. Applicants explain aspect ratio as the ratio of the longest dimension of a three-dimensional particle to the shortest dimension. Generally, the high aspect ratio antimicrobial in the shape of flakes or sheets as well as those that are in the shape of fibers or cylinders. Other

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shapes, such as football and other oblong shapes may be suitable as well.

Trogolo, has disclosed above, teaches an antibiotic coated substrate having an antibiotic coating composition coated thereon. Trogolo does not disclose the microcapsule comprise a dopant, specifically sodium nitrate. Michal discloses a method of providing a therapeutic, diagnostic or lubricious hydrophilic coating on and intra-corporeal medical device (abstract). Additionally, nitric oxide donor drugs may be used as a vasodilator relaxing smooth muscles of a vessel prior to, during, and/or after angioplasty or stent placement. A variety of suitable nitric-oxide donor drugs include sodium nitrate (col. 4). Absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Trogolo by adding a dopant specifically sodium nitrate as taught by Michal because of the expectation of relaxing smooth muscles of a vessel prior to, during, and/or after angioplasty or stent placement. Both Trogolo and Michal teach medical devices, specifically stents coated with a hydrophilic polymer. Therefore, it would have been obvious to add sodium nitrate to the composition of Trogolo for the added benefits taught by Michal. The expected result would be a microcapsule comprising a hydrophilic polymer, an antimicrobial agent and a dopant.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure US 6046243, US 6296834, and US 6290962.

The arts are considered pertinent to the instant application as the inventors have used particles and microcapsules and zeolites.

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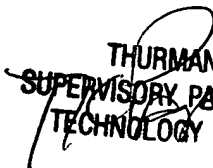
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

7/20/05


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600